

California State Board of Pharmacy

1625 North Market Blvd., N219, Sacramento, CA 95834 Phone (916) 574-7900 Fax (916) 574-8618 www.pharmacy.ca.gov STATE AND CONSUMER SERVICES AGENCY DEPARTMENT OF CONSUMER AFFAIRS ARNOLD SCHWARZENEGGER, GOVERNOR

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LEGISLATION AND REGULATION COMMITTEE January 8, 2007, 9:30 a.m. Department of Consumer Affairs Hearing Room 1625 North Market Blvd. Sacramento, CA 95834

This committee meeting is open to the public and is held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting the board's office at (916) 574-7900, at least five working days prior to the meeting.

Opportunities are provided to the public to address the committee on each open agenda item. Board members who are not on the committee may attend the meeting as observers.

Agenda

*Times are approximate and are subject to change

A. Call to Order 9:30 a.m.

B. Approved Regulations

- 1. Amend 16 CCR 1793.7 and add CCR 1793.8 Pharmacy Technician Checking Pharmacy Technicians in an Acute Care Hospital Setting
- 2. Repeal 16 CCR 1717(e) and add CCR 1713 Prescription Drop Boxes and Automated Self-Use Delivery Device for Refill Prescriptions

C. Board Adopted Regulations – Pending Administrative Review

- 1. Proposed Repeal of 16 CCR 1717.2 Notice of Electronic Prescription Files
- 2. Proposed Adoption of 16 CCR 1784 Self-Assessment of a Wholesaler by a Designated Representative-in-Charge

D. Board Approved Regulations Currently Noticed – Action Recommended at January 2007 Board Meeting

- 1. Proposed Amendment of 16 CCR 1706.2 Abandonment of Application Files
- 2. Proposed Amendment to 16 CCR 1775.4 Reschedule of an Office Conference to Contest a Citation

E. Board Approved Regulations Awaiting Notice

- 1. Section 100 Changes
 - Proposed Amendment to 16 CCR 1709.1 Replace the term "Exemptee-in-Charge" with "Designated Representative-in-Charge"

- Proposed Amendment to 16 CCR 1780 Update the USP Standards Reference Material
- Proposed Amendment to 16 CCR 1780.1 and 1781 Replace the term "Exemptee" with "Designated Representative"
- Proposed Repeal of 16 CCR 1786 Return of Exemption Certificates
- 2. Proposed Amendment to 16 CCR 1760 Disciplinary Guidelines

F. Board Approved Regulation Awaiting Conformance with California Building Standards Rulemaking Process

Addition to the California Building Code – 24 CCR 490A.3 and 505.12.2 Related to Compounding Parenteral Solutions; Technical Changes to the Building Code Relating to Pharmacies

G. Board Approved Regulations – Proposed Language to be Developed

- 1. Proposed Regulation on the Process and Criteria to Approve Accreditation Agencies for Pharmacies.
- 2. Notice to Consumers Currently under review by the Public Education Committee for refinement.

H. Requests for Legislation and Regulatory Proposals for 2007

1. Proposed Legislation

- a. Ominbus Provisions
 - Adulterated or Counterfeit Drugs or Dangerous Devices B&PC section 4084
 - Wholesaler: Bonding Requirements B&PC sections 4162 and 4162.5
 - Citation and Fine for Repository and Distribution Programs for Dangerous Drugs B&PC sections 4314 and 4315
 - Temporary License Fees for Wholesalers B&PC section 4160(f) and 4161(k)
 - Intern Pharmacist License B&PC section 4208
 - Voiding of License When Licensed Premises Remains Closed B&PC 4312
- b. Proposed Changes to AB 2986 (Chapter 286, Statutes of 2006)
- c. Licensing of Headquarters for Chain Pharmacies

2. Proposed Regulations

- a. Section 100 Changes
 - Self Assessment Forms 16 CCR 1715
 - Pharmacy Technicians in Hospitals 16 CCR 1793.8
- b. Proposed Addition to 16 CCR 1785 Self-Assessment of a Veterinary Food-Animal Drug Retailer

I. Public Requests for Future Legislation and Regulatory Proposals

The public is encouraged to bring to the meeting copies of proposed language, an explanation of the problem, and how the proposed language would correct the problem.

J. New Business

Adjournment 12:00 noon

Committee materials will be available on the board's Web site by January 3, 2007.